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| EXAMINER | |
|---|---|
| JONES, DAMERON LEVEST | |
| **ART UNIT** | **PAPER NUMBER** |
| 1618 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/694,243 | BAO ET AL. | |
| | Examiner | Art Unit | |
| | D. L. Jones | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 9/20/07.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-4,6-52 and 87-96 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-4,6-52 and 87-96 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**ACKNOWLEDGMENT**

1. The Examiner acknowledges receipt of the amendment filed 9/20/07 wherein claims 1, 7, 10, 26, 39, 87, 88, 95, and 96 were amended and claims 5 and 53-86 were canceled.

***Note***: Claims 1-4, 6-52, and 87-96 are pending.

**RESTRICTION INTO GROUPS**

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 9 (in part), 38 (in part), 88 (in part), 95 (in part) and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is HIV-TAT, classified in class 424, subclass 1.69.

II. Claims 9 (in part), 38 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is HSV-VP22, classified in class 424, subclass 1.69.

III. Claims 9 (in part), 38 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is ANTP, classified in class 424, subclass 1.69.

IV. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle

compositions wherein the intracellular delivery ligand is SEQ ID NO: 4, classified in class 424, subclass 1.69.

V. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 5, classified in class 424, subclass 1.69.

VI. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 6, classified in class 424, subclass 1.69.

VII. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 7, classified in class 424, subclass 1.69.

VIII. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 8, classified in class 424, subclass 1.69.

IX. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 9, classified in class 424, subclass 1.69.

X. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 10, classified in class 424, subclass 1.69.

XI. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 11, classified in class 424, subclass 1.69.

XII. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 12, classified in class 424, subclass 1.69.

XIII. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 13, classified in class 424, subclass 1.69.

XIV. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 14, classified in class 424, subclass 1.69.

XV. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle

compositions wherein the intracellular delivery ligand is SEQ ID NO: 15, classified in class 424, subclass 1.69.

XVI. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 16, classified in class 424, subclass 1.69.

XVII. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 17, classified in class 424, subclass 1.69.

XVIII. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 18, classified in class 424, subclass 1.69.

XIX. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 19, classified in class 424, subclass 1.69.

XX. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 20, classified in class 424, subclass 1.69.

XXI. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 21, classified in class 424, subclass 1.69.

XXII. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 22, classified in class 424, subclass 1.69.

XXIII. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 23, classified in class 424, subclass 1.69.

XXIV. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 24, classified in class 424, subclass 1.69.

XXV. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle compositions wherein the intracellular delivery ligand is SEQ ID NO: 25, classified in class 424, subclass 1.69.

XXVI. Claims 10 (in part), 39 (in part), 88 (in part), 95 (in part), and 96 (in part), drawn to compositions and methods thereof comprising nanoparticle

compositions wherein the intracellular delivery ligand is SEQ ID NO: 26, classified in class 424, subclass 1.69.

***Note***: Claims appearing in more than one group will only be examined to the extent that they read on the elected invention.

**LINKING CLAIMS**

3. Claims 1-4, 6-8, 11-37, 40-52, 87, and 89-94 link(s) inventions I-XXVI. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1-4, 6-8, 11-37, 40-52, 87, and 89-94. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

***Note***: It should be noted that claims are linking claims. Thus, the linking claims will be examined with the elected invention.

4. The inventions are distinct, each from the other because of the following reasons: Inventions I-XXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions each require distinct intracellular peptides that are structurally different from one another and require a separate search strategy. Thus, prior art which anticipates or renders obvious one group would neither anticipate nor render obvious another group even though the peptides classify in the same area.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

**ELECTION OF SPECIES**

6. Claims 1-4, 6-52, and 87-96 are generic to the following disclosed patentably distinct species: nucleic acids, antibodies/antibody fragments, aptamers, high affinity

ligands, and peptides/polypeptides. The species are independent or distinct because a search of one species would neither anticipate nor render obvious another species; the species require separate search strategies, and the species are structurally different. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

**Applicant is respectfully requested to elect a single disclosed species from within the elected group above. Specifically, if appropriate for the elected group, Applicant is requested to elect: the targeting probe(s), the detectable moiety/moieties, the biocompatible coating(s), the magnetic nanoparticle, metal coating, and second delivery ligand.**

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

10. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

11. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**COMMENTS/NOTES**

13. This office action is deemed necessary in order to advance prosecution of the instant application.

14. It should be noted that the groups above include the products and methods thereof.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. L. Jones
Primary Examiner
Art Unit 1618

November 25, 2007